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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/974,584	11/19/1997	THOMAS R. CECH	015389-00295	8401
34151	7590	10/13/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP 8TH FLOOR TWO EMBARCADERO CENTER SAN FRANCISCO, CA 94111			MYERS, CARLA J	
		ART UNIT	PAPER NUMBER	
			1634	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/974,584	CECH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 August 2006 and 04 August 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 119, 127 and 129-131 is/are pending in the application.
- 4a) Of the above claim(s) 127 and 131 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 119, 129 and 130 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/3/06.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicant's arguments and amendments set forth in the response of August 4, 2006 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. In particular, the rejection of claim 119 and 129 under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,309,867) is withdrawn in view of the 132 Declaration of Calvin Harley filed August 3, 2006. The rejection of claim 119 under 35 USC 112 first paragraph (new matter) has been obviated by the amendment to delete the recitation of "with the proviso that said protein is not a mouse telomerase reverse transcriptase protein, characterized as having at least 500 consecutive amino acids encoded by SEQ ID NO: 124" and to recite therefor "with the proviso that the polynucleotide does not contain consecutive nucleotides 1-2009 of SEQ ID NO: 124." Support for this amendment may be found, for example, at page 167 of the substitute specification filed February 27, 2001.

***Election/Restrictions***

2. It is noted that the response requests rejoinder of withdrawn claims 127 and 131 upon the determination that the product claims are patentable. However, claims 119, 129 and 130, drawn to the elected product, have not been found to be allowable. Accordingly, claims 127 and 131 are withdrawn from consideration as being drawn to a non-elected invention.

***Information Disclosure Statement***

3. In the information disclosure statement filed August 3, 2006, the citation to a declaration listing other issued patents and pending applications has been lined through

because such a declaration is not properly listed in information disclosure statements. The declaration is not a published document and does not have a publication date or publication source. However, the declaration has been considered by the Examiner.

### **Maintained Rejections**

#### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 119, 129 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 and 7-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '836 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '836. In particular, the present

claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '836 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 224 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 224 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '836 are encompassed by the presently claimed polynucleotides encoding any TRT.

5. Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 29, 32-33 and 99-121 of copending Application No. 09/721,477. Although the present claims and the claims of '477 are not identical, they are not patentably distinct from each other because the present claims and the claims of '477 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-50 of copending Application No. 10/877,124. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '124 are both inclusive of nucleic acids encoding a human TRT having 10 or more amino acids of SEQ ID NO: 2. The present claims are also encompassed by

the claims of '124 which are inclusive of nucleic acids encoding SEQ ID NO: 2 and having a mutation that reduces telomerase activity since the present claims encompass variants having 60% identity with a sequence encoding hTRT.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 29, 32-33 and 1-33 and 36-40 of copending Application No. 10/044,539. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '539 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 75-78, 102, 105-108 of copending Application No. 09/721,506. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '506 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26 and 28 of copending Application No. 11/207,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '078 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 19-33, 39-43, 47-57 of copending Application No. 10/044,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '692 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 119, 129 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,927,285. Although the conflicting claims and the claims of '285 are not identical, they are not patentably distinct from each other because the present claims and the claims of '285 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

12. Claims 119, 129 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,921,664. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '644 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

13. Claims 119, 129 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,337,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '200 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

14. Claims 119, 129 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,475,789. Although the conflicting claims and the claims of '789 are not identical, they are not patentably distinct from each other because the present claims and the claims of '789 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

15. Claims 119, 129 and 130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,444,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '650

are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

### **Response to Arguments**

16. In the response filed August 4, 2006, Applicants state that it is not necessary to address the above rejections as they apply to U.S. Application Nos. 09/721,477, 11/207,078 and 10/044,692 because these applications are less advanced in prosecution and are not expected to issue prior to the present application. This argument has been fully considered but is not persuasive. First it is noted, that a provisional obviousness-type double patenting rejection may be withdrawn if it is the only remaining rejection in the application and if the other copending application has a later filing date. However, in the present situation, the obviousness-type double patenting rejections over applications '477, '078 and '692 are not the only remaining rejections in the application because the claims are also rejected under obviousness-type double patenting over other copending applications and patents. Further, as set forth in MPEP 804 (1), a terminal disclaimer is still required in a later filed application before the ODP can be withdrawn and the application can be permitted to issue. In the present situation, it has not been established that the claims of each of applications '477, 078, and '692 have a later filing date. Additionally, as stated in the MPEP 804 (1):

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the

application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

The response further states that the remaining patents and applications will be addressed "under separate cover." However, the Office has not received a supplemental response addressing the remaining obviousness-type double patenting rejections. Accordingly, each of the obviousness-type double patenting rejections are maintained for the reasons stated above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla,

can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers  
October 4, 2006

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER